PART K

COMPLIANCE PROCEDURES

Sec. K.1 General

a. Definitions

"Applicant" means a Person seeking a certificate, license or registration issued under the provisions of the Act and the requirements of the regulations.

“Certificate” is an official document issued by the Agency which authorizes a person to perform a specified radiation activity.

“Exemption” means an exclusion from a regulatory requirement granted by the Agency or Authority. When the exclusion is based on a national standard or similar documented and publicly available information, the Agency may grant it. Otherwise, the exemption shall be referred to the Authority for consideration.

"Hearing" means a proceeding to examine an application or other matter before the Authority in order to adjudicate rights, duties, or privileges.

"Imminent Radiation Hazard(s)" means an imminent hazard exists when the radiation levels that exist are in excess of three times the regulatory limit.

“License” means a license issued by the Agency in accordance with the regulations.

“Licensee” means any person who is licensed by the Agency in accordance with the regulations and the Act.

“Licensee’s Representative” means a person who has been authorized by the licensee to represent them during activities or proceedings governed by the regulations.

“Modification” means a change in the specification of a machine or radiation facility.

"Notice of violation" means a written statement of one or more alleged infringements of a legally binding requirement. The notice normally requires the licensee, registrant, other permit holder to provide a written statement describing the following:

(1) corrective steps taken by the licensee, registrant, or other permit holder, and the results achieved;

(2) corrective steps to be taken to prevent recurrence; and

(3) the projected date for achieving full compliance. The Authority may require responses to notices of violation to be under oath.

“Registration” means to enroll or register with the Agency in accordance with the regulations.

“Regulations” mean all parts of the Delaware Radiation Control Regulations (DRCR) and all parts of the Delaware Radiation Technologist Certification Regulations (RTCR).

"Severity level" means a classification of violations based on relative seriousness of each violation and the significance of the effect of the violation on the occupational or public health or safety.

"Violation" means an infringement of any rule, certificate, license or registration condition, order of the agency, or any provision of the Act.

b. General requirements

i. No person shall use/operate a source of radiation or radiation facility who does not possess a valid certificate, license or registration issued or renewed to that person by the Agency in accordance with DRCR B.4**,** B.7, B.9**,** C.1**,** C.33 or RTCR VII A of the regulations. Only a person who complies with the requirements of the regulations shall be entitled to receive or retain such a certificate, license or registration.

ii. The owner/manager of a radiation facility shall designate a Radiation Safety Officer (RSO) in accordance with the regulations.

iii. All facility licenses, registrations and Radiation Technologist Certificates must be posted in a conspicuous location.

iv. Any action taken by the Agency against an applicant or certificate, license or registration holder may be appealed to the Authority on Radiation Protection.

Sec. K.2 Types of Certificates, Licenses or Registrations

a. Certificate

i. A Radiation Technologist Certificate is required to practice radiation technology (Request Application Form ORC-R16) as outlined in the Delaware Radiation Technologist Certification Regulations.

ii. A Plan Approval Certificate is required for the construction or modification of a radiation facility (Request Shielding Information Letter) as outlined in Part B.4 of the regulations.

b. License

A Radioactive Material License is required to use and/or possess a source of Naturally Occurring/Accelerator Produced Radioactive Material (NARM) as defined in Part A.2 of the regulations (Request Application Form ORC-R2).

c. Registration

i. A Registration is required to possess and/or use a radiation machine (i.e. x-ray equipment) or operate a radiation facility. (Request Application Form ORC-R1)

ii. A Registration is required to possess a source of Byproduct/Atomic Energy Act Material. (Request Application Form ORC-R2)

iii. A Registration is required to perform a radiation service, but not limited to, repair, install or calibrate radiation equipment, devices, perform health physics consultations or surveys and personnel dosimetry (Request Application Form ORC-R3). For radon testing or mitigation (Request Application Form ORC-R4).

d. Annual/Biennial License or Registration

An annual or biennial license or registration shall be issued to any person desiring to possess, use, provide or operate a source of radiation, radiation facility or radiation service in the State for more than thirty (30) days upon written application to the Agency.

i. The Agency shall issue a license or registration to the applicant if the Agency's inspection or examination reveals that the proposed facility, use, source of radiation and/or individual complies with the requirements of the regulations.

ii. An annual/biennial license or registration is valid for one (1) or two (2) anniversary year(s) from the date of issuance, unless a new owner, management, firm or lessee takes possession of the facility, source of radiation or service; or the license or registration is revoked by the Authority for violations of the regulations. A license or registration is not transferable.

d. Temporary License or Registration

This license or registration allows for the temporary use of an out-of-state radiation source or performance of a radiation service in Delaware.

i. X-ray equipment - send advance written notice to the Agency as per Part B.13 of the regulations.

ii. Radioactive (NARM) Source/Device - send advance written notice to the Agency of the intended use and location as per Part C.90 of the regulations.

<u>Sec. K.3 New Construction, Renovation, Change of Ownership, Management, Firm or Lessee</u>

a. A valid certificate, license or registration is not transferable. Therefore, it is the responsibility of the new owner/manager to acquire an operating certificate, license or registration prior to commencing operations.

b. New construction or modification of an existing room or area associated with a source of radiation requires plan approval in accordance with Part B.4 of the regulations.

c. The owner/manager of a radiation source is responsible for notifying the Agency prior to its sale, transfer, lease, or disposal in accordance with Part B.12., C.1 or D.1 of the regulations.

d. If any renovations or modifications of the physical structure of the existing facility are required, based on current or previous inspection reports of the Agency, the new owner/manager will be held responsible for these renovations or modifications. Completion of any renovations shall be achieved prior to the start of operation, unless the new owner/manager is granted an exemption in accordance with Part A.3 of the regulations.

Sec. K.4 Inspections

a. Inspection Frequency:

An inspection of a registered facility shall be performed once every twelve (12) months for medical including osteopathy, chiropractic, podiatric and veterinary facilities and every twenty-four (24) months for other registered facilities. Additional inspections of registered facilities as described in the regulations shall be performed as often as necessary to ensure and verify compliance with the regulations.

b. Access:

The Authority or its duly authorized representatives shall have the power to enter at all reasonable times upon any private or public property for the purpose of determining whether or not there is compliance with or violations of 16 Del. C., Ch.74 and rules and regulations issued thereunder, except that entry into areas under the jurisdiction of the federal government shall be effected only with the concurrence of the federal government or its duly authorized designated representative. The Agency may suspend for a period not to exceed (30) days, the certificate, license or registration to operate/use a source of radiation for refusing access to the representative(s) of the Agency if the Agency can show good cause that there is a risk of imminent harm to the public from ionizing radiation at the facility to which the Agency is attempting access.

c. Inspection Report Form:

i. Facility Inspection Form ORC-R11 shall be used to record the results of inspections at x-ray, NARM or Byproduct facilities as specified in Part K.4. (d) of the regulations. The co-signed original of the completed inspection report form shall be furnished to the person named on the license or registration or the Radiation Safety Officer (RSO) at the conclusion of the inspection. The completed inspection form shall list the violation(s) (if any), give the time period for correcting the violation(s) and state the corrections to be made. The inspection report form shall summarize the requirement(s) of the regulations. The form shall also state that "Failure to comply with time limits for correction of any violations cited in this notice shall result in automatic license or registration suspension and immediate cessation of use of a source radiation or radiation area in accordance with Part K.7 of the regulations of the Authority on Radiation Protection."

ii. The completed inspection report form is a public document that shall be made available for public disclosure to any person who requests it in accordance with the "Freedom of Information Act 29 Del. C., Ch. 100."

iii. A Notice of Violation (Form ORC-R10) must be posted in a conspicuous location until the violation has been corrected.

d. Types of Inspections:

Inspections are performed to verify compliance with all applicable laws and regulations.

i. Regular Inspections:

Regular inspections are performed on a routine basis in permanent, operating, registered facilities. These inspections shall address all items on the inspection report form. Items in violation shall be recorded by item number.

ii. Follow-up Inspections:

Follow-up inspections shall be performed when a regular inspection finds one (1) or more Severity Level 1 violation(s) or three (3) or more Severity Level 2 violations.

Follow-up inspections may also be performed to verify proper posting of certificates, licenses or registrations, after complaint and investigation inspections, or after administrative hearings.

iii. Complaint Inspections:

Complaint inspections are performed in response to formal or informal complaints against registered facilities. A complete inspection may be performed by the Agency in the interest of protecting the public. (e.g. DRCR D.301, D.302, D.801 and RTCR Section V.)

iv. Investigation Inspections:

Investigation inspections are performed on non-registered radiation facilities for determining whether compliance with the regulations is required.

v. Other Inspections:

The inspections include construction/modification, pre-operational and other inspections not included above. (e.g. DRCR B.4, J.16.)

Sec. K.5 Correction of Violations

Violations of the regulations have been classified as Severity Level 1 and Severity Level 2 depending upon the impact of the violation. In general, Severity Level 1 violations could result in overexposure to the patient or operator or violate individual's rights as outlined in the regulations. Severity Level 2 violations generally will not result in overexposure but may

indicate a lack of administrative controls over the use of the radiation source. Reference Appendix A for violation classifications.

a. Severity Level 1 Items:

i. When one (1) or two (2) Severity Level 1 items of violation are found by any inspection, the related source(s) of radiation shall be tagged "out-of-use." All violations shall be corrected prior to returning the unit in service.

ii. When three (3) or more Severity Level 1 items of violation are found by any inspection, the certificate, license or registration shall be suspended in accordance with Part K.7.(b)(1) of the regulations. All violations shall be corrected prior to resuming registered activities.

iii. The licensee or registrant shall inform the Agency in writing within 10 days of issuance of the inspection report of the proposed method or means of correcting the Severity Level 1 violation(s) and of the date when the correction will be made.

iv. Follow-up inspections shall be conducted within 30 days to assure correction.

b. Severity Level 2 Items:

i. All Severity Level 2 items shall be corrected as soon as possible, but in any event, within 60 days.

ii. Follow-up inspections shall be conducted within 60 days to assure corrections have been completed.

c. If a follow-up inspection of a registered facility indicates non-compliance of a previously cited violation of the last inspection, a hearing before the Authority on Radiation Protection shall be scheduled. Additionally, the Agency may file a complaint to the Authority.

Sec. K.6 Fees RESERVED

Sec. K.7 Procedure for Administrative Action by Agency

If the Agency determines that condition(s) exist(s) in a registered facility which represent(s) a threat to life or a serious risk of damage to health, safety and welfare of the workers or public, or if serious violations, repeat violations, or general disregard of accepted radiation practice are found to exist, administrative action is required.

a. Compliance Conference:

A meeting held by the Agency with management of a licensee, registrant, or other license, certificate or registration holder to discuss the following:

i. safety, safeguards, or environmental problems;

ii. compliance with regulatory, license condition, or registration condition requirements;

iii. proposed corrective measures including, but not limited to, schedules for implementation; and

iv. enforcement options available to the agency.

b. Suspension of Certificate, License or Registration

i. Conditions for Suspension of Certificate, License or Registration

If some condition(s) is/are determined to exist in a registered facility which present(s) an imminent radiation hazard to human health, the Agency may cease operations of the source of radiation without a hearing or written notice until such time the conditions have been corrected. Further enforcement action shall be taken in accordance with the regulations. Such an imminent radiation hazard shall include, but is not limited to, any one of the following:

(1) The existence of three (3) or more Severity Level 1 items.

(2) Failure to correct any Severity Level 1 item within thirty (30) days.

(3) The absence of a licensed practitioner in a healing arts facility.

(4) The absence of a Radiation Safety Officer.

The suspension shall be effective upon receipt of written notice by the Radiation Safety Officer or the person in charge of the radiation facility or their agent. A suspension statement recorded on the inspection report by the Agency constitutes a written notice. Service of a written notice of suspension by the Agency stating the reason(s) for the suspension must be made by the close of the following business day. The certificate, license or registration shall not be suspended for a period longer than necessary to correct the hazardous conditions, unless mutually agreed upon.

ii. Right of Appeal of Suspension

The owner/manager of the registered facility may submit in writing an appeal to the Authority on Radiation Protection for reconsideration of a decision by the Agency. The notice of appeal shall be sent via certified mail to the Authority on Radiation Protection and to the Agency. An appeal shall not automatically stay the decision of the Agency. After review for potential radiation hazard to the public, the suspended or revoked license or registration may be stayed on the order of the Program Administrator for Radiation Control. If a notice of appeal is not filed within thirty (30) days, the license or registration suspension or revocation recommendation shall be upheld and other enforcement action taken in accordance with the regulations. If the notice of appeal is timely filed, the Authority on Radiation Protection shall hold a hearing at its earliest opportunity.

c. Reinstatement of Certificate, License or Registration:

i. In consultation with the Authority on Radiation Protection, if a follow-up inspection by a representative of the Agency shows the imminent radiation hazard(s) to human health no longer exist(s), the suspension shall be lifted immediately and the certificate, license or registration returned.

ii. If there is no evidence that the imminent radiation hazard(s) has/have been corrected, the suspension will remain in effect until the condition(s) has been corrected.

iii. The owner/manager of the registered facility may request, in writing, a hearing before the Authority on Radiation Protection at any time during the period of suspension, for the purpose of demonstrating that the imminent radiation hazard(s) no longer exist. The request for hearing shall not stay the suspension.

iv. A record of all proceedings shall be made in accordance with Part K.9 of the regulations.

d. Exemption Requests

i. All requests for exemptions must be filed with the Agency for review. If a determination cannot be made by the Agency, the exemption request must be referred to the Authority. Agency may grant if based on national standards.

ii. Shall hear an appeal by the applicant within ten (10) days following the denial of an exemption request by the Agency. If an exemption is granted; record of the action shall become a part of the permanent record of the facility.

iii. An exemption is not transferable.

Sec. K.8 Administrative Action by the Authority

a. Administrative Hearings

The Authority may, upon sworn complaint or upon its own initiative, cause an investigation to be held to determine whether a license or registration holder, former license or registration holder or applicant has engaged in any activity requiring disciplinary action. Upon completion of said investigation, the Authority shall hold a hearing to determine whether a license or registration holder, former license or registration holder or applicant has engaged in activities specified in this section as grounds for disciplinary action. The Authority shall fix the time and place for the hearing.

i. The Authority shall cause a copy of the charges, together with a notice of the time and place for the hearing, to be served on the alleged violator at least 15 days prior to the date fixed for the hearing. When personal service cannot be effected, the Agency shall mail a copy of the charges and of such notice to the alleged violator at his last known address according to the records of the Agency.

ii. In all proceedings herein:

(1) The alleged violator may be represented by counsel who shall have the right of examination and cross-examination.

(2) The alleged violator and the Agency may call witnesses and admit documentary evidence on their own behalf.

(3) Testimony before the Authority shall be under oath. Any member of the Authority shall have power to administer oaths for this purpose.

(4) A record of the hearing shall be made. At the request and expense of either party such record shall be transcribed with a copy to the other party.

(5) The decision of the Authority shall be based upon a preponderance of the evidence. If the charges are supported by such evidence, the Authority may revoke, refuse to issue, or suspend a certificate, license or registration, or otherwise discipline the individual. A suspended certificate, license or registration may be reissued upon a further hearing initiated at the request of the suspended licensee by written application in accordance with the rules of the Authority and if the Authority finds compliance has been achieved.

b. Revocation and Appeal of Suspended Certificate, License or Registration

The Authority on Radiation Protection, at its earliest opportunity, shall consider the Agency's recommendation for certificate, license or registration revocation or hear an appeal by the owner/manager whose permit stands suspended. The Authority on Radiation Protection shall, at each scheduled meeting, release the name(s) and address(s) of those registered facilities currently meeting the following criteria:

i. Certificate, License or Registration permanently revoked

ii. Certificate, License or Registration suspended

iii. Certificate, License or Registration censored

iv. Issued a letter of reprimand

v. Certificate, License or Registration application refused

vi. Certificate, License or Registration renewal refused

vii. Use of source of radiation terminated

c. Exemptions referred to the Authority

The Authority on Radiation Protection:

i. May from time to time grant written permission to vary from particular provisions set forth in the regulations when the extent of the variation is clearly specified and it is documented to the Authority's satisfaction that:

(1) Such variation is necessary to obtain a beneficial use by the owner/manger of an existing facility;

(2) Appropriate alternative measures have been taken to protect the health and safety of the public from ionizing radiation and assure that the purpose of the provisions from which the variation is sought will be observed.

ii. Shall hear an appeal by the applicant within ten (10) days following the denial of an exemption request by the Agency. If an exemption is granted; record of the action shall become a part of the permanent record of the facility.

iii. An exemption is not transferable.

Sec. K.9 Agency Emergency Actions

(a) Inspection/Enforcement

i. A registered facility may be inspected by the Agency as often as necessary for enforcement of the regulations.

ii. Registered facilities, their employees and their agents shall be in compliance with the regulations. The established administrative procedures for the implementation and enforcement of the provisions and penalties of 16 Del. C., Ch, 74, shall be applicable to this section.

(b) Failure to allow access, inspection or tests by the Agency representative(s) shall cause theAgency to prohibit the use of a source of radiation, close the registered facility, and/or suspend the facility certificate, license or registration if the Agency can show good cause to believe that there is a risk of immediate harm to the public from ionizing radiation at the facility to which the Agency is attempting access.

(c) Procedure when Overexposure/Radiation Contamination is Suspected:

When the Agency has reasonable cause to suspect possible individual overexposure or radioactive contamination (e.g. DRCR D.101-D.106) at a registered facility, it may conduct a radiation investigation which can indicate exposure histories of individuals or make any other investigations as indicated and shall take appropriate action. The Agency may require any or all of the following measures:

i. The immediate closing of the registered facility or prohibition of the use of a radiation source or radiation area until, in the opinion of the Agency, no further danger of overexposure or contamination exists.

ii. Restriction of an employee(s) services to some area of the radiation facility where there would be no opportunity to use a source of radiation or be irradiated.

iii. Any other action which the Agency can demonstrate is necessary to protect the health of the public and other employees of the radiation facility.

Sec. K.10 Court Penalties

a. Any person who violates a provision of the regulations and any person who is the holder of a certificate, license or registration or who otherwise operates a registered facility that does not comply with the requirements of the regulations shall be subject to the provisions of 16 Del. C. Section 7416.

b. Operation without a Certificate, License or Registration:

If a facility or individual is found operating without a valid certificate, license or registration as required by DRCR B.5. or C.1. or RTCR, Section VII of the regulations, the Agency may act on behalf of the Authority and the source of radiation shall be tagged out-of-use.

c. The Agency may seek to enjoin violations of the regulations.

d. A conspicuous notice shall be prominently displayed on the radiation source or at all entrances of facilities meeting the following criteria:

i. Failed to obtain a valid certificate, license or registration; or

ii. Certificate, License or Registration suspended; or

iii. Certificate, License or Registration revoked.

APPENDIX A
VIOLATION CLASSIFICATION
(Typical/Not all inclusive)
LICENSING RADIOACTIVE MATERIALS
EXEMPT RADIOACTIVE MATERIALS

Facility

Severity Level 1

1. Operating without a permit K.1.b.
2. Personnel Overexposure D. 201
3. Radiation Levels Excessive D. 601; 602
4. Personnel Monitoring D. 502

Severity Level 2

1. Registration Form 16. Del. C. 7402, K.1.d.
2. Notice to Employees J.11.c.
3. Safety Procedures F.3.a.
4. Personnel Monitoring Records D.1107.

General Licenses

Severity Level 1

1. Possession of non-exempt radioactive material C.4
2. Operations not immediately suspended for failed or damaged device C.22.a.iii.(5)
3. Radioactive device abandoned C.22.a.iii.(6)
4. Transfer or disposal of device to an unauthorized recipient C.22.a.iii.(7)
5. Manufacture of devices pursuant to a general license C.22.a.iv.
6. Possession, use, transfer of unauthorized form/quantity of NARM for diagnostic purposes pursuant to a G.L. C.22.d.

Severity Level 2

1. Registration Form 16. Del. C. 7402, K.1.d.
2. Device not tested for leakage or proper operation at 6 month intervals C.22.a.iii.(2)
3. Tests and servicing not performed per instructions or by authorized person C.22.a.iii.(3)
4. Tests and service records not kept for at least 2 years C.22.a.iii.(4)
5. Report of failed or damaged device to Agency within 30 days of event C.22.a.iii.(5)
6. Report of device transfer or disposal to Agency within 30 days of event C.22.a.iii.(7)

APPENDIX A
VIOLATION CLASSIFICATION

General Licenses

Severity Level 2

7. Possession, use, transfer of unauthorized form or quantity of NARM for In-Vitro testing pursuant a G.L. C.22.e.

8. Failure to transport/store NARM in accordance with the requirements of U.S. Department of Transportation pursuant to a G.L. C.23

9. Failure to report radiation incident, theft, loss of licensed material C.22.a.iii.(9)

10. Unauthorized possession, use, transfer, manufacture or disposal of Ra-226 calib./ref. source pursuant to a G.L. C.22.c.

APPENDIX A
VIOLATION CLASSIFICATION

Medical Uses

Severity Level 1

1. Radiation detection/measurement instrumentation not in accordance with C.26.c.i.(4)

2. Receipt, possession, use of form of NARM for Group I, II, IV, V not in accordance with C.26.c.ii.(1)

3. Receipt, possession, use of generator/reagent kit for Group III not in accordance with C.26.c.ii.(2)

4. Receipt, possession, use of NARM container for Group VI not in accordance with C.26.c.ii.(3)

5. Use of leaking/contaminated source not in accordance with C.26.c.ii.(5)(c)

6. Use of leaking/contaminated calibration/ reference source not in accordance with C.26.c.v.(3)

7. Degree of assurance the RA-226 needles/cells remain close not in accordance with C.26.c.ii.(5)(f)

8. Degree of assurance that Radium patients remain in hospital not in accordance with C.26.c.ii.(5)(g)

9. Receipt, possess, use of calibration/reference source that exceeds authorized quantity not in accordance with C.26.c.i.(4)

10. Transfer of NARM to recipient not in accordance with C.40

Severity Level 2

1. Radiation safety operating procedures not in accordance with C.26.c.i.(5)

2. Use of Group III generator/kit not in accordance with C.26.c.ii.(4)

3. Testing of Group VI NARM source/device 100+ microcuries with half life 30+ days not in accordance with C.26.ii.(5)(a)

4. Degree of occurrence that Group VI test for detecting 0.005 uCi or if Rn 0.001 uCi not in accordance with C.26.ii.(5)(b)

5. Failure to report leaking/contaminated source not in accordance with C.26.c.ii.(5)(c)

6. Detection capability of leak test for calibration/reference source not in accordance with C.26.c.v.(2)

7. Attempt to follow/maintain instructions for source/container not in accordance with C.26.c.ii.(5)(d)

8. Attempt to follow/maintain instructions for calibration/reference source not in accordance with C.26.c.vi.(1)

9. Conduction/maintenance of quarterly record of inventory for sources not in accordance with C.26.c.ii.(5)(e)

10. Conduction of quarterly inventory and maintenance and maintenance of records not in accordance with C.26.c.vi.(2)

11. Leakage/contamination test of calibration/ reference source with half-life 30+ days not in accordance with C.26.c.ii.(5)

APPENDIX A
VIOLATION CLASSIFICATION

Medical Uses

Severity Level 1

. 11. Patient exposure (ESE) not in accordance with F.3.a.ix.

. 12 Tube support not in accordance with F.4.g.

. 13. Technique indicators not in accordance with F.4.h.

. 14. Multiple tube indication not in accordance F.4.f.

. 15. Gonadal shielding not in accordance with F.3.a.vi.

. 16. Operator apron/barrier not in accordance with F.3.a.v.(2)

Severity Level 2

12. Conduction of NARM activity via reciprocity not in accordance with C.90

13. Maintenance of x-ray system records not in accordance with F.3.a.xii.

14. Speed of film/screen not in accordance with F.3.a.ix.

15. Technique chart not in accordance with F.3.a.iii.

16. Warning label not in accordance with F.4.a.

17. Patient dose of 1 gray (100 rads) or more not reported to the Agency F.5.k.

Radiographic

Severity Level 1

1. Location of x-ray controls not in accordance with F.6.b.v., F.7.c.v.

2. Position indicating device not in accordance with A.10

. 3. Beam Collimation not in accordance with F.7.b.

. 4. Filtration deficiency of 0.2+ mm not in accordance with F.4.e.i.

5. Variation in timer linearity of 15% or more not in accordance F.6.b.iv, F.7.c.iv.

6. Variation in exposure reproducibility of 15% or more not in accordance with F.6.d., F.7.d.

. 7. Total misalignment of x-ray/light field edges of 5% or more not in accordance with F.6.a.ii.(1).

Severity Level 2

1. Visual/audio signal not in accordance with F.6.b.ii, F.7.c.ii.

2. Adjustment of x-ray field not in accordance with F.6.a.i.

3. Indication of field size, upon adjustments, not in accordance with F.6.a.ii.

4. Means to limit source to skin distance not in accordance with F.7.a.

5. Filtration deficiency of 0.2 mm or less not in accordance with F.4.e.i.

6. Variation in timer linearity more than 10% but less than 15% not in accordance with F.6.b.iv, F.7.c.iv.

7. Variation in exposure reproducibility more than 5% but less than 10% not in accordance with F.6.d., F.7.d.

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VIOLATION CLASSIFICATION

Radiographic

Severity Level 1

8. Total misalignment of x-ray beam/image receptor centers of 5% or more not in accordance with F.6.a.ii.(1).

9. Discorrespondence of indicated x-ray field with beam limited x-ray field of 5% or more not in accordance with F.6.a.ii.(3).

Severity Level 2

8. Total misalignment of light/x-ray field edges more than 2% but less than 5% not in accordance with F.6.a.i.(2).

9. Total misalignment of x-ray beam/image receptor centers more than 2% but less than 5% not in accordance with F.6.a.ii.(1).

10. Discorrespondence of indicated x-ray with beam limited x-ray field more than 2% but less than 5% not in accordance with F.6.ii.(3).

Fluoroscopic

Severity Level 1

1. Activation of x-ray production not in accordance with F.5.b.

2. Annual exposure rate measurement not in accordance with F.5.c.i.(4).

3. Exposure rate not in accordance with F.5.c.

4. Useful beam protective barrier not in accordance with F.5.d.

5. Limitation of x-ray field to image receptor not in accordance with F.5.a.

6. Minimum field at maximum SID not in accordance with F.5.a.

7. High level control exposure rate limit not in accordance with F.5.c.

8. Timing device not in accordance with F.5.g.

9. Control of scattered radiation not in accordance with F.5.h.

10. Failure to report patient dose of 1+ gray to the Agency F.5.k.

Severity Level 2

1. Posting of exposure rate measurements not in accordance with F.5.c.

2. Measurement records and posting of same not in accordance with F.5.c.

3. Adjustment of field not in accordance with F.5.a.ii.

4. Means of field adjustment not in accordance with F.5.a.ii.

5. Indication of kV and mA not in accordance with F.5.e.

6. Means to indicate that beam is perpendicular to image receptor not in accordance with F.5.a.

7. Audible signal to reset not in accordance with F.5.g.

8. Minimum source to skin distance not in accordance with F.5.f.

9. Exposure rate due to transmission through primary barrier not in accordance with F.5.d.

APPENDIX A
VIOLATION CLASSIFICATION

INDUSTRIAL RADIOGRAPHIC

Severity Level 1		Severity Level 2
1. > 2 mR/hr.	Failure to maintain radiation level from device < 4" in diameter below maximum allowable limit of 50 mR/hr. at 6" in accordance with E.101.	≤ 2 mR/hr.
2. > 2 mR/hr.	Failure to maintain radiation level from device > 4" diameter below maximum allowable limit of 200 mR/hr. at surface in accordance with E.101.	≤ 2 mR/hr.
3. > 2 mR/hr.	Failure to maintain radiation level from storage container below maximum allowable limit of 200 mR/hr. at the surface in accordance with E.101.	≤ 2 mR/hr.
4. > 2 mR/hr.	Failure to maintain radiation level from storage container below maximum allowable limit of 10 mR/hr. at a distance of 1 meter in accordance with E.101.	≤ 2 mR/hr.

Locking of Source

5. Radiation Source Storage Container was found unlocked and not under the direct surveillance of authorized individual in accordance with E.102.a.

6. Exposure device and/or storage container was not locked during transit or prior to unit being made secure as required by E.102.b.

7. Device was not physically secured to prevent tampering or removal as required by E.103.

APPENDIX A
VIOLATION CLASSIFICATION

Survey Instruments

Severity Level 1

1. Failure to adequately maintain survey instruments in accordance with E.104.a.

2. Survey meter not capable of detecting 2-1000 mR/hr. as required by E.104.a.

Severity Level 2

1. Failure to possess calibrated back up instrument E.104.a.

2. Failure to conduct quarterly calibrations in accordance with E.104.b.

3. Failure to calibrate unit after servicing in accordance with E.104.b.i.

4. Failure to achieve accuracy of (± 20%) as required by E.104.b.ii.

5. Failure to calibrate each scale using 2 points other than zero as required by E.104.b.iii.

6. Failure to maintain calibration records for two years in accordance with E.104.c.

Leak Testing/Repair

Severity Level 1

1. Service to sealed source not conducted by authorized individual in accordance with E.105.a.

2. Failure to immediately withdraw contaminated unit from service to effect decontamination/repair as required by E.105.d.

3. Failure to properly label unsecured source in accordance with E.105.e.

Severity Level 2

1. Failure to conduct leak test within 6 month interval as required by E.105.b.

2. Leak test procedure not capable of detecting unit 0.005 uCi of removable contamination as required by E.105.b.

3. Failure to record test results in microcuries as required by E.105.c.

4. Failure to notify agency within 5 days of receiving test results as required by E.105.d.

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VIOLATION CLASSIFICATION

Inventory/Inspection

Severity Level 1

1. Failure to perform quarterly operational safety maintenance and inspection in accordance with E.108.b.

2. Failure to withdraw defective unit from service as required E.108.c.

3. Failure to conduct and record alarm tests at the beginning of each period of use as required by E.109.b.

Severity Level 2

1. Failure to conduct quarterly inventory as required by E.106

2. Failure to maintain utilization log as required by E.107

3. Failure to log required information in accordance with E.107.a.-d.

4. Failure to properly document quarterly inspection and maintenance of radiation devices in accordance with E.108

5. 19. Failure to record and maintain test results in accordance with E.109

Limitations/Procedures/Controls

Severity Level 1

1. Individual is not qualified Industrial Radiographer as defined by) E.201.a.i., ii., iii.

2. Individual is not a qualified radiographer's trainee as defined by E.201.b.

3. Qualified operator(s) not wearing personal monitoring devices as required by E.203.a.

4. Operating and Emergency procedures do not meet the requirements of E.202.a.-g.

Severity Level 2

1. Failure to maintain training and test records in accordance with E.201.c.

2. Failure to record dosimetry data in accordance with E.203.b.

Precautionary Procedures

Severity Level 1

1. Failure of qualified operators to maintain direct surveillance in accordance with E.301

2. Failure to have calibrated and operable survey instrument available in accordance with E.303.a.

Severity Level 2

1. Failure to post required information in accordance with E.302

2. Failure to maintain survey records for 2 years in accordance with E.303.f.

APPENDIX A
VIOLATION CLASSIFICATION

Precautionary Procedures

Severity Level 1

3. Failure to conduct physical radiation survey in accordance with E.303.b. and/or E.303.c.

4. Failure to maintain records at temporary job site in accordance with E.304.a.-f.

Severity Level 2

Special Requirements

Severity Level 1

1. Failure to meet requirements for enclosed radiography in accordance with E.305.a.

2. Failure to meet exemption requirements and maintain unit in accordance E.305.b.

Severity Level 2

1. Failure to maintain evaluation records for 2 years in accordance with E.109.b.

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Use of Sealed Sources

Severity Level 1

1. Failure to store sealed source(s) in protective enclosure in accordance with G.21.

2. Failure to conduct leak test in accordance with G.21.

3. Failure to immediately withdraw defective unit from service in accordance with G.21

4. Failure to measure or calculate maximum radiation level at a distance of 1 meter from patient and record in accordance with G.27

5. Failure to determine radiation levels, document and maintain records in accordance with G.26.

Severity Level 2

1. Failure to conduct quarterly inventory and maintain records in accordance with G.21.

2. Failure of test procedures to detect 185 Bq. (0.005 uCi) of contamination in accordance with G.21.

3. Failure to record test results as required by G.21.

4. Failure to post required information in accordance with G.39.

5. Failure to record information required by G.39 on patient chart

APPENDIX A
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Analytical

Severity Level 1

1. Failure to provide safety device in accordance with H.3.a.
2. Failure to provide warning devices in accordance with H.3.b.
3. Failure to install shutter in accordance with H.3.e.
4. Failure to construct tube housing in manner which ensures compliance with H.3.f.
5. Failure to obtain Radiation Safety Officer's approval for by-passing safety device in accordance with H.5.a. & b.
6. Failure to provide and/or ensure the use of extremity dosimeters in accordance with H.6.b.
7. Failure to instruct and/or ensure operator competence in accordance with H.6.a.

Severity Level 2

1. Failure to label equipment in accordance with H.3.d.
2. Failure to have appropriate warning lights in accordance with H.3.b.
3. Failure to provide protective cabinet to prevent leakage in accordance with H.3.g.
4. Failure to conduct Radiation Surveys in accordance with H.4.b.
5. Failure to document survey record in accordance with H.4.b.
6. Failure to post area in accordance with H.4.c.
7. Failure to secure unused ports in accordance with H.3.c.

APPENDIX A
VIOLATION CLASSIFICATION

Particle Accelerators

Limitations

Severity Level 1

1. Operator did not receive radiation safety instruction or could not demonstrate understanding of radiation safety I.6.a.

2. Operator unable to demonstrate competency in the use of the accelerator I.6.a.

Severity Level 2

1. Operator had not received copies Parts D, I, J, & emergency procedures I.6.a.

2. Radiation Safety Committee/Radiation Safety Officer is not authorized to terminate operations as per I.6.b.

Controls/Interlocks

Severity Level 1

1. HRA not provided with Interlock as per I.8.b.

2. Interlock does not require manual reset I.8.e.

3. Safety interlocks not independently wired I.8.c.

4. All safety interlocks are not fail safe I.8.d.

5. Scram buttons not located in HRA I.8.f.

Severity Level 2

1. Instrumentation and controls are not clearly identified I.8.a.

2 Scram buttons do not require manual reset I.8.f.

3. Not all HRA entrances are equipped with warning lights as per I.9.a.

4. Not all HRA are equipped with audible warning devices which activate for 15 seconds I.9.b.

5. HRA barriers/pathways are not identified per D.203; I.9.c.

APPENDIX A
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Operating Procedures

Severity Level 1

1. Particle accelerator not unsecured from unauthorized use I.10.a.

2. Bypass of safety interlock not authorized by Radiation Safety Officer and/or Radiation Safety Committee or not recorded and posted as per I.10.e.

Severity Level 2

1. Safety interlocks are used as routine "off" switch I.10.b.

2. Electrical circuit diagram not maintained and available I.10.d.

3. Current operating and emergency procedures are not kept at control panel I.10.f.

4. Record of quarterly safety device operability check are not available I.10.c.

Radiation Monitoring

Severity Level 1

1. Radiation protection survey not performed and/or documented by an approved person following operation or facility changes I.11.b.

2. Radiation levels not continuously monitored in all HRAs as per I.11.c.

Severity Level 2

1. Portable monitoring equipment not available, operable and calibrated I.11.a.

2. All area monitors are not calibrate annually I.11.d.

3. Periodic surveys of airborne particulates are not performed as per I.11.e.

4. Periodic Smear Surveys are not conducted for contamination as per I.11.f.

5. All area surveys are not performed according to proper written procedures as per I.11.g.

6. Current records of all surveys and tests were not available at facility I.11.h.

APPENDIX A
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Ventilation Systems

Severity Level 1

1. Means are not provided to ensure compliance with Part D airborne concentrations I.12.a.

2. Airborne concentrations in excess of Part D limits were discharged to an uncontrolled area I.12.b.

APPENDIX A
VIOLATION CLASSIFICATION

Notice and Reports to Workers

Posting of Notices

Severity Level 1

Severity Level 2

1. Parts D and J of DRCR not posted J.11.a.
2. Facility radiation permit/document not posted J.11.a.
3. Radiation operating procedures not posted J.11.a.
4. Notice of violation for radiological working conditions not posted J.11.a.
5. Notice to employees, Agency Form X not posted J.11.c.
6. Violations not posted within five (5) days nor remain posted for at least (5) days J.11.d.
7. Documents do not appear in sufficient number of conspicuous places J.11.e.

Instructions to Workers

Severity Level 1

1. Workers were not instructed to report any conditions that could cause unnecessary exposure to radiation J.12.a.
2. Workers were not instructed about warnings for unusual occurrence or malfunction that may involve exposure to radiation J.12.a.
3. Workers were not advised of radiation exposure reports pursuant to J.12.a.

Severity Level 2

1. Workers were not kept informed of radiation sources J.12.a.
2. Workers were not instructed of health protection problems associated with radiation exposure J.12.a.
3. Workers were not instructed to observe applicable parts of DRCR J.12.a.

APPENDIX A
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Notifications

Severity Level 1

1. Written report of specified Radiation exposure data are not given to the worker J.13.a.

2. Workers are not furnished a radiation exposure report within 30 days after the licensee becomes informed of exposure or termination of employment J.13.c.

Severity Level 2

1. Workers are not advised annually of their radiation exposure pursuant D.1107.a., J.13.b.

2. As required pursuant to D.1202, D.1203, or D.1204, exposed individuals are not provided a report of their radiation exposure as per J.13.d.

Representatives of Registrant/Workers

Severity Level 1

1. Agency not afforded opportunity to inspect equipment and activities J.14.a.

2. Agency not permitted to consult with workers privately J.14.b.

3. Worker authorized representative not given opportunity to accompany agency during inspection of physical working conditions J.14.c.

4. Worker representative does not meet qualifications set forth in routine radiation J.14.d.

5. Different facility/worker representatives not permitted to accompany agency on inspection J.14.e.

6. Mutually agreed upon "outside" individual(s) was not permitted to accompany agency inspectors J.14.f.

7. Worker(s) was not allowed to privately consult with the Agency inspector about perceived radiological condition J.15.b.

8. A worker has been discharged or discriminated against for filing a radiological complaint on behalf of himself or others J.16.c.

APPENDIX A
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Therapeutic Radiation Machines

Severity Level 1	Severity Level 2
1. All non-compliance with the requirements of Part X are Severity Level 1 violations.	